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# Using codesign to develop a mobile application for pelvic floor muscle training with an intravaginal device (femfit®)

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## Abstract

**Aims:** The aim of this project was to use codesign to develop a mobile application (app) for pelvic floor muscle training, with an intravaginal device (femfit®). The objective was to obtain user feedback to guide the design and development of a mobile app, consistent with the Mobile Application Rating Scale (MARS) framework.

**Methods:** Twenty-six women (22–62 years) provided mobile app feedback using a Design Thinking framework and grounded theory approach. Four focus groups (2 h each) and two sets of one-to-one interviews (1 h each) were held from May 2018 to October 2019. The researchers debriefed the focus groups and interviews, and undertook analysis based on project objectives and key questions.

**Results:** Recurring themes throughout the study aligned with sections of the MARS: (A) engagement (e.g., progress tracking), (B) functionality (e.g., intuitive interface), (C) aesthetics (e.g., smart graphics and colors), (D) information (e.g., clear, concise information). An internal preliminary assessment determined a MARS Quality Mean Score of 4.1 of 5 (engagement: 3.6 of 5; functionality: 4 of 5; aesthetics: 4.3 of 5: information: 4.4 of 5).

**Conclusions:** The development of the mobile app is on track to meet MARS requirements, and to be a fun, motivating app for women. Future work is required to investigate its efficacy.

**KEYWORDS**
digital health, female, incontinence, mobile application, pelvic floor

## 1 | INTRODUCTION

It is well-recognized that pelvic floor muscle training (PFMT) can resolve symptoms of stress urinary incontinence for women. There is Level 1 Grade A evidence showing one-to-one pelvic floor physiotherapy is effective treatment,[1] however, this is not feasible on a population basis; long wait times and high expense are some of the barriers restricting access.[2] Up to 60% of women do not seek help for urinary incontinence,[3] yet their quality of life is significantly diminished.

Digital health is growing, accelerated by the Covid-19 worldwide pandemic. There is scope for this to be applied to pelvic floor muscle (PFM) health. Mobile applications (apps) for medical self-management are on the rise, with an estimated 325,000 health apps equating to 3.7 billion downloads in 2017, an increase of 16% on 2016.[4] There is Level 2 evidence that mobile technologies for

conservative self-management of urinary incontinence can be beneficial, improving symptoms, and PFMT adherence.[5]

A search of mobile apps for patients with pelvic floor disorders in Apple iTunes and Google Play stores revealed 4127 apps, yet only 12 apps that met specified eligibility criteria (the app had to be in English, pertinent to the search term, patient-centered, and accurate) cited scientific evidence or expert source.[6] Most pelvic floor mobile apps are developed without regulated guidelines, and lack scientific evaluation. The findings from Sudol et al.[6] show that when searching for apps, it is difficult for patients to find relevant, accurate information.

Biofeedback is a tool that can be used alongside PFMT to assist the patient to be more aware of muscle function, and to enhance and motivate their training. An external sensor produces biofeedback to indicate what is happening from inside the body. It can be visual, auditory, or both.[7] There is a range of pelvic floor devices that provide biofeedback, for clinic or home use. However, there is no clear evidence that biofeedback-assisted PFMT is better than, or equivalent to, one-to-one pelvic floor physiotherapy (Grade of Recommendation: B). Further research is required to validate the usefulness of these devices, and their corresponding biofeedback.[1]

It is proposed that a mobile app, used alongside an intravaginal pressure sensor device (femfit®), that provides real-time visual biofeedback, will guide women to effectively locate and exercise their PFM, and self-guide through a training program. The femfit® has been used in university-based research studies worldwide, with positive preliminary feedback.[8–10] However, further investigation is required to ensure the femfit® is suitable for long-term home use. This study builds on previous findings using iterative design and refinement.

The aim of this project was to use codesign to develop a mobile app for PFMT with an intravaginal device (femfit®). The objective was to obtain user feedback to guide the design and development of a mobile app, consistent with the Mobile Application Rating Scale (MARS) framework.

## 2 | STUDY DESIGN

This study used Design Thinking and qualitative, iterative framework methodologies.[11] A range of potential users was engaged to create a product that would fit into differing lifestyles. This holistic approach considered each person's varied experiences and attitudes, rather than urinary incontinence being the sole focus. One-to-one sessions and focus groups were used to gather information about perceptions and attitudes towards an intravaginal biofeedback device (femfit®) and to develop its associated mobile app. Ethical approval was obtained through The University of Auckland Human Participants Ethics Committee, Protocol Number 022043.

## 3 | MATERIALS

The femfit® is an intravaginal pressure sensor array that transmits pressure via Bluetooth to display real-time biofeedback on a mobile app.[12] It comprises eight pressure sensors encapsulated in biocompatible silicon. It is flexible and comfortable, so does not obstruct natural movement during a PFM contraction. The femfit® has been manufactured to the ISO13485 medical device quality standard. The app is an integral part of the femfit® system as it displays the data from the femfit®, provides feedback to users on progress with exercising their PFM, and assists with adherence, motivation and engagement. The PFMT program is evidence-based and clinically relevant, guiding the user through 12 weeks of graduated exercises.[13,14]

## 4 | METHODOLOGY

A grounded theory approach was used to conduct this qualitative research (Figure 1).[11] Four focus groups (2 h each) and two sets of one-to-one interviews (1 h each) were held between May 2018 and October 2019.

### 4.1 | Recruitment

Twenty-six women (22–62 years) were recruited through relevant social media (e.g., mother's groups and pelvic floor community pages), selected due to their desire to actively manage their PFM health. Inclusion criteria were women, over 18 years old, comfortable using an intravaginal device, and own a smart mobile phone. Participants were excluded if they were familiar with the project (e.g., must not be part of the wider research team, had not taken part in any previous usability studies or research trial, before Focus Group 1). There were no exclusions based on medical conditions for the focus groups, but at the time of trialling the device during the one-to-one interviews women could not be pregnant, menstruating, have any vaginal infections, or a bulging pelvic organ prolapse. Where possible, the same women were used for successive focus groups (and the one-to-one interview) to build on their PFM knowledge and app exposure, allowing for iterative design.

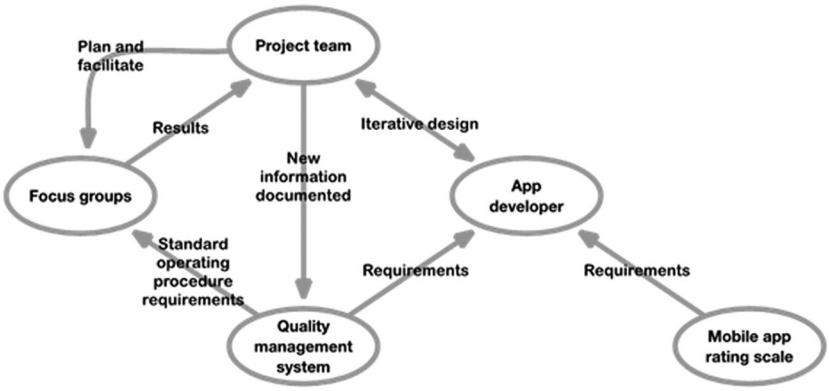


**FIGURE 1** Flowchart of the multidisciplinary iterative design process for mobile app development

## 4.2 | Focus groups

Four focus groups were repeated at different phases of the app development process. Topics included introducing the femfit® as a prototype (Focus Group 1, May 2018, $n = 8$), identifying desirable app criteria (Focus Group 2, September 2018, $n = 7$, $n = 6$, held over two evenings), testing the app prototype (Focus Group 3, April 2019, $n = 8$) and gathering feedback on the exercise protocol (Focus Group 4, October 2019, $n = 8$). A facilitator and an observer (Kathryn Nemec, Jennifer Kruger, and Laura Pedofsky) hosted each focus group. Four women attended all four focus groups, two women attended two focus groups, and 17 women attended only one focus group. Those who attended multiple sessions were able to see the app progress. At the beginning of each focus group expectations were set (e.g., speak one at a time, respect opinions, confidentiality), followed by the overall purpose of the focus group, the session format, and how participants' views would be used. The facilitator guided the discussion based on a semistructured guide with open-ended questions to explore predefined topics and themes, adapted from the MARS document.[15] Interaction and discussion between group members was actively facilitated to keep conversations relevant and adhere to a time schedule. The discussion was also audio recorded.

## 4.3 | One-to-one interviews

Interviews were conducted with twelve participants (November–December 2018); nine were from the focus groups who expressed a willingness to be involved further, and three were new to the study. The interviews were part of a wider investigation to understand the overall usability of the femfit® device and app. Participants each cleaned, inserted, and exercised using their own femfit® (with the app). The main focus was to assess how effectively the app conveyed information about the PFMT protocol. Similar to the focus groups, recorded interviews were held with a facilitator (interviewer) and an observer present. A template was followed to address pre-determined objectives, which aligned with the MARS document. One-to-one interviews enabled participants to engage directly with the femfit® device and app, followed up with detailed in-depth discussion.

## 4.4 | Data analysis

The researchers debriefed the focus group and interviews, and undertook analysis based on project objectives and key questions. Qualitative data analysis methodologies were used to identify recurring statements and key themes. Topics that emerged from the discussion, but not itemized in the guide, were also included. A report for each focus group and set of interviews was prepared. Identified themes were then described to the app developers, and adapted for each app iteration.

## 4.5 | MARS quality mean score

The MARS assesses app quality on four dimensions. All items are rated on a five-point scale from (1) Inadequate to (5) Excellent. As this study was part of a codesign process, and the app was not finalized at study completion, it was not appropriate for participants to score the app using MARS; an internal preliminary assessment (not independent) did so instead.

# 5 | RESULTS

Recurring themes throughout the study aligned with sections of the MARS: (A) engagement (e.g., progress tracking), (B) functionality (e.g., intuitive interface), (C) aesthetics (e.g., smart graphics and colors), and (D) information

(e.g., clear, concise information). Results from each session are summarized in Table 1. Focus group summaries are categorized according to MARS sections (Table 2).

In addition to the categorical data in Table 2, the discussion raised further important requirements and expectations relating to the femfit® system. All participants were open to the idea of using the femfit® and app for home PFMT. Although there are already PFMT apps available, the majority of participants had not used these. One participant had used the *NHS Pelvic Floor* app, although she did not use it regularly, as it "required effort" and there was "no feedback". Participants were familiar with mobile apps in general

**TABLE 1** Qualitative findings from the usability study

| Co-operative design approach with aim (introduced by the facilitator) and summary | |
|---|---|
| Focus group 1 | Aim: Introduce prototype device, app, and PFMT |
| | Positive response to the concept of real-time PFM biofeedback. Key themes discussed: |
| | • Information: PFM health and exercises; display progress of PFM strength change |
| | • Data security and sharing: FDA (or equivalent) approval would assist app reputability; opt-in to share data with others for example clinician |
| | • Additional features: aesthetic interface; motivational; reminder notifications |
| Focus group 2 | Aim: Introduce an initial app wireframe and gather feedback for app features |
| | Discussed criteria: intuitive, reliable, useable, motivational, look/feel. User requirements: |
| | • Information needs to be clear, concise, and accurate |
| | • Exercises to be novel, personalized, with clinical evidence |
| | • Ability to view progress towards goals set by a user |
| | • Games to make the app approachable, fun, and nonmedical |
| | • An online femfit community (opt-in) was welcomed. No interest for in person meet-ups |
| Focus group 3 | Aim: Gather feedback on app development to date; identify areas to improve/modify |
| | Overall, impressed with app progress to date. Improvements areas identified: |
| | • Bluetooth connection must be reliable |
| | • Instructional information and real-time biofeedback requires refinement |
| | • More information on PFM anatomy and how the app gamification works |
| | • Timing and motivational feedback while undertaking PFMT |
| Focus group 4 | Aim: Gather feedback about the exercise protocol and evaluate the onboarding process |
| | Participants continued to raise minor queries (e.g., large print settings) but overall, the app was well received |
| | • Positives: the interface is visual and clear; fun and feminine (compared to other exercise apps); app navigation is intuitive |
| | • Risk identified: potential to develop a familiar, but incorrect pattern for exercising PFM was questioned |
| | • Onboarding: content is as users would expect, with minor amendments |
| One-to-one interview | Aim: Assess women's reaction to biofeedback and the exercise protocol effectiveness |
| | Participants excited by real-time biofeedback and found the data motivating and empowering |
| | • Understood how the app could be used to work towards goals |
| | • Valued visual feedback and muscle differentiation |
| | • Background information to be simplified. Audio could help |
| | • Biofeedback game was hard! Emphasis required that this is exercises are only a guide |
| | • Some concern that if the femfit was positioned incorrectly, biofeedback is meaningless |
| | • Further information is required before the exercises, for example, how to play the game/do a PFM contraction? |

Abbreviations: FDA, Food and Drug Administration; PFM, pelvic floor muscle; PFMT, pelvic floor muscle training.

TABLE 2 Results according to Mobile App Rating Scale (MARS) sections

| MARS section | Results from participants according to MARS sections |
|---|---|
| Section A: Engagement | • App content presented in an interesting and engaging way, for example, description of exercises and the gamification is good entertainment<br>• Increased customization for personal preferences, for example, sound, content, notifications would be useful<br>• An option of sharing with clinicians and an online community will likely increase engagement |
| Section B: Functionality | • App is easy to learn how to use<br>• Practice pages enable users to understand how to do the PFM exercises<br>• Icons, buttons and menu are clear, and moving between the screens is logical, accurate, and appropriate, with intuitive links between the screens |
| Section C: Aesthetics | • App is visually appealing, fun, and it stands out from other apps. The colors enhance the app features and menus<br>• Arrangement and size of information, buttons, icons, menu and content on the screen is well designed<br>• Screen is uncluttered and information is easy to find, select, see and read |
| Section D: Information | • App content is well written, correct, easy to understand, and relevant. It is comprehensive but concise<br>• Links to more information and resources on the femfit® website should be available where appropriate. This applies to any instructions (insertion, practice, exercises), information, and any content that guides users through the app<br>• Biofeedback data is too complicated, for example, "I'm not sure what I am looking at" |

Abbreviation: PFM, pelvic floor muscle.

and referenced popular apps such as Apple Health, Spotify, and WhatsApp. Participants defined key criteria for the femfit® app to be intuitive, reliable, usable, motivational, with good aesthetic. They wanted the app to feel familiar, and convey a supportive environment. Overarching brand values such as trust could also be communicated through the app. Instructions and information about the femfit®, and any graphics, should be clear and intuitive, providing users with immediate feedback. Participants who had sought healthcare professional PFM treatment in the past commented that they had found the prescribed exercises intense. In this app, they desired simplified instructions, variety, and evidence-based protocols. They noted that information regarding exercise history and gamification are app features that will help with motivation and compliance.

During one-to-one interviews, it was obvious that although the women had stated they wanted the app to have clear, concise information, researchers had underestimated this. There was some feedback that the biofeedback data was too complicated, and tried to convey too much information at once, with comments such as "I" m not sure what I am looking at." This showed that although focus group discussion can highlight key design parameters, hands on app (and device) use is imperative to evaluate the effectiveness of the implementation.

The idea of a clinical portal, with a health professional having access to PFM pressure data, was raised in Focus Group 1, and recurred throughout. It was suggested this opt-in biofeedback could work alongside a pelvic floor physiotherapist, or personal trainer, with an ability to personalize exercise programs. One participant was a Pilate's instructor who showed interest in using the app during classes.

Independently from clinical contact, an online femfit® community (between users) was proposed, similar to an online forum or social media group. There was no interest for in-person meetups. There was concern about losing anonymity when connecting with other users, and careful consideration is needed to both manage identity and personal information, and provide confidence that this is managed appropriately. The intimate condition of urinary incontinence must be approached with care in the online space (akin to creating a safe space during the study).

### 5.1 | MARS quality mean score

Overall, a MARS Quality Mean Score of 4.1 of 5 was determined (engagement: 3.6 of 5; functionality: 4 of 5; aesthetics: 4.3 of 5; information: 4.4 of 5). The MARS framework will continue to be central to the assessment of ongoing app iterations.

## 6 | DISCUSSION

Focus groups facilitated interaction and discussion about the different app topics, revealing potential users' questions, concerns, and overall user experience. One-to-one interviews offered detailed insight using the femfit® device and app

together. Recurring themes identified throughout the study aligned with MARS document sections: (A) engagement, (B) functionality, (C) aesthetics, and (D) information. Future studies will assess the app using MARS for comprehensive, quantitative analysis.

There is some qualitative research documenting user experiences for app-based treatments for urinary incontinence, identifying preferences, interactions, and success factors.[16,17] However, these studies have women assessing the mobile app after it has been created, or at least well on its way through development. This paper documents the first mobile app design and development for PFMT with input from potential users from the outset, following up with regular, iterative codesign throughout the project. This novel research forms a solid app structure, as well as creating the opportunity for the femfit® to be a home self-treatment. Long-term, the codesign iterative process will also accelerate the app development timeline and enhance functionality.

Focus group methods can make an important contribution to sensitive research.[18] They give voice to sections of the community who frequently remain unheard, in a safe space, for the disclosure of experiences or behaviors, which (in other contexts) could be taboo. As individuals' behavior in the group setting could be influenced by the presence of other group members, researchers were conscious of creating a permissive and safe space to encourage participants to share their experiences. This is relevant to women who experience urinary incontinence and whose voice is "silenced" by personal vulnerability or societal stigma. The focus groups provided valuable insight into the complexities and nuances of developing the femfit® app, how members of the group may interact with it, and their relationship with it—along with insight into the diversity of individuals. Advantages include the relatively low cost and speed of the results from the focus group. During the one-to-one interviews, similar themes emerged as raised in the focus groups, suggesting participants felt safe to speak their opinions during a group setting.

The femfit® MARS Quality Mean Score (4.1 of 5) is comparable to other top-scoring PFMT apps such as Squeezy NHS Pelvic Floor App (Quality Mean Score of 4.32 of 5 and 4.1 of 5), Tät (Quality Mean Score of 4.16 of 5 and 4.1 of 5) as evaluated by expert reviewers.[19,20] However, there is an opportunity for improvement in all four sections. Similar to the femfit® app, both the Squeezy NHS Pelvic Floor App and the Tät scored lowest for Section A: Engagement; the femfit® app lacks customization and interaction. The focus groups discussed ideas to improve interaction, but these are difficult to implement when creating a prototype. Further femfit® app iterations will include increased customization with notifications, as well as clinician and online community interaction. Research shows that online fitness communities can create behavior change for increased adherence, and this could be applied to PFMT.[21]

## 6.1 | Study limitations

Participants recruited were homogeneous (e.g., lived in similar neighborhoods, with similar education and health literacy levels). The project objective was to obtain app feedback, so no personal information on PFM status was collected. Thus, these women may have different responses to those who experience urinary incontinence, or have varied demographic information. Although it was helpful to use the same women in successive focus groups to build on acquired knowledge, complacency (familiarization) may affect their feedback. Thus, additional participants were recruited during the study. Researchers will continue to undertake user experience testing to widen participants' demographic strata with the aim of converging opinions to optimize app improvement.

Topics in the semi-structured discussion guide aligned with sections of the MARS document. In the future, for increased robustness, additional scoring systems could be used in parallel to evaluate the femfit® app. For example, APPLICATIONS Scoring System is designed to facilitate bias-free reviews of apps in women's healthcare, has been applied to several areas of women's health, with limited evidence of its use in PFM health.[6] APPLICATIONS provides a high-level overview, lacking detail present in MARS. The technology acceptance model (TAM) is an established system, developed due to concern that health workers were not using Information Technology. The two main themes assess users' IT uptake: "perceived usefulness" and "perceived ease of use" therefore, there is scope to see if TAM could assist with PFMT adherence.[22]

It should be noted that end user engagement in a codesign process is iterative and is much more than acquiring a set of user requirements. An end-user request that exercises should not be too intense does lead to a requirement for easy exercises, but to the need to provide education around how the intensity relates to building strength and the need to progress with intensity as capability improves.

## 6.2 | Future work

Lack of adherence is a major barrier to PFMT success. Although some evidence suggests mobile apps can assist with this, a systematic review of women's expectations and experiences with e-Health found lack of motivation was still a barrier for home treatment. Verhoeks et al.[23]

propose a blended approach, suggesting some clinical guidance could enhance adherence. Future work, from both user experience and software development perspectives, is required to determine how blended care would interface. Clinical input would likely increase expense, so a careful balance is required to ensure the low-cost advantage of apps is not lost.

To score highly in health app scoring systems (e.g., MARS) there is a requirement to undertake clinical assessment and provide evidence. Scientific evaluation of mobile apps for PFMT is limited with just one randomized control trial in published literature; mobile app Tät is evaluated by 123 women. This study was complete with a 2-year follow up, interviews, and a cost-effective analysis for the app.[24,25] This comprehensive investigation provides the scientific rigor this study space requires. Upon completion of the femfit® app development, the utility of the app will be tested, with and without the femfit® device. PFMT apps that meet reputable scoring system requirements, combined with robust research, will enable patients to access gold standard treatment from home. Clinicians will also have increased confidence in recommending evidence-based apps for their patients.

## 7 | CONCLUSIONS

Mobile health app design and development is enhanced when using Design Thinking ideologies. Study participants responded positively to the idea of using a mobile app (and femfit® device) for home pelvic floor muscle training, and gave feedback that aligned with the Mobile App Rating Scale. Future work (e.g. clinical studies) is required to verify mobile app efficacy while used in conjunction with the femfit®.

### ETHICAL APPROVAL

This study has been approved by the University of Auckland Human Participants Ethics Committee; Protocol Number 022043.

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### CONFLICT OF INTERESTS

Laura Pedofsky has no conflict of interest or financial disclaimer to declare. David Budgett, Poul M. F. Nielsen, Jennifer Kruger hold shares in JUNO-FEM LTD.

### PRESENTATION AT PRIOR CONFERENCE

The preliminary results of this study were presented at International Continence Society (ICS) Online 2020.

### AUTHOR CONTRIBUTIONS

Laura Pedofsky: *project development, data collection and analysis, and manuscript writing*. Poul M. F. Nielsen: *project development and manuscript editing*. David Budgett: *project development and manuscript editing*. Kathryn Nemec: *project development, data collection, and analysis*. Chantal Dumoulin: *project development and manuscript editing*. Jennifer Kruger: *project development, data collection, and manuscript writing*.

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